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\* Admitted in TX only  
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\*\*\* Passed Patent Bar Exam

July 29, 2004

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Re: U.S. Patent Application No.: 10/618350  
For: *METHODS AND COMPOSITIONS FOR PREVENTING OXIDATIVE  
DEGRADATION OF PROTEINS*  
Inventors: Cini, John K. *et al.*  
Filed: July 11, 2003  
Our Ref. No.: MXI-285

Dear Sir:

I enclose herewith for filing in the above-identified application the following:

1. Information Disclosure Statement;
2. PTO Form SB-08;
3. Copies of non US patent and US patent publication references cited in PTO Form SB-08 (C1-C20);
4. A copy of the International Search Report; and
5. A Return Postcard.

No additional costs are believed to be due in connection with the filing of this Information Disclosure Statement. However, please charge any necessary fees in connection with the enclosed statement to our Deposit Order Account No. 12-0080. For this purpose, a duplicate of this sheet is attached.

I hereby certify that this correspondence is deposited with the United States Postal Service as first class mail in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450:

July 29, 2004

Date

Danielle L. Herritt, Esq., Reg. No. 43,670

Respectfully submitted,  
LAHIVE & COCKFIELD, LLP

Danielle L. Herritt  
Registration No. 43,670  
Attorney for Applicants



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Cini, John K. *et al.*

Serial No.: 10/618350

Filed: July 11, 2003

For: *METHODS AND COMPOSITIONS FOR  
PREVENTING OXIDATIVE DEGRADATION OF  
PROTEINS*

Attorney Docket No.: MXI-285

Group Art Unit: 1614

Examiner: Not Yet Assigned

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Certificate of First Class Mailing (37 CFR §1.8(a))

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on the date set forth below.

July 29, 2004  
Date of Signature and of Mail Deposit

By: [Signature]  
Danielle L. Herritt  
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Attorney for Applicants

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Applicants and their Attorney are aware of the following publications and information, listed on the attached PTO Form SB-08, and in accordance with 37 CFR §1.97 hereby submit these publications for the Examiner's consideration.

A copy of the International Search Report (ISR) mailed April 9, 2004 in corresponding International Application No. PCT/US03/22012 is attached. The references cited in the ISR are cited in PTO Forms SB/08 (References A2 & C15).

Copies of cited U.S. patents and U.S. publications (Reference ID Nos. A1-A8) are not enclosed with this statement in accordance with the waiver published in the USPTO Official Gazette on August 15, 2003. Copies of foreign patent documents and non-patent literature (Reference ID Nos. A9-B13) are enclosed in accordance with 37 CFR 1.98(a)(2).

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, Applicants understand that the Examiner will make an independent evaluation of the cited publications.

Under 37 CFR § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 CFR §1.17(p) to our Deposit Order Account No. 12-0080.

Respectfully submitted,  
LAHIVE & COCKFIELD, LLP



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Date: July 29, 2004

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PTO/SB/08a/b (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

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<b>Substitute for form 1449A/B/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/618350
				Filing Date	July 11, 2003
				First Named Inventor	Cini, John K.
				Art Unit	1614
				Examiner Name	Not Yet Assigned
Sheet	1	of	2	Attorney Docket Number	MXI-285

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	A1	4,522,811	06-11-1985	Eppstein <i>et al.</i>	
	A2	5,217,954	06-08-1993	Foster <i>et al.</i>	
	A3	5,217,890	06-08-1993	Daggett	
	A4	6,482,799 B1	11-19-2002	Tusé <i>et al.</i>	
	A5	2001/0051595 A1	12-13-2001	Lyons <i>et al.</i>	
	A6	2002/0068346 A1	06-06-2002	Krystek <i>et al.</i>	
	A7	2003/0114362 A1	06-19-2003	Gruner <i>et al.</i>	
	A8	2003/0073808 A1	04-17-2003	Quirk <i>et al.</i>	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C1	Ahmed <i>et al.</i> "Nonenzymic Reactivation of Reduced Bovine Pancreatic Ribonuclease by Air Oxidation and by Glutathione Oxidoreduction Buffers." <i>J Biol Chem.</i> 250(21):8477-8482(1975)	
	C2	Akers, "Antioxidants in Pharmaceutical Products." <i>J. Par. Sci Tech.</i> 36:222-228(1982)	
	C3	Amado <i>et al.</i> "Dityrosine: <i>In Vitro</i> Production and Characterization." in <u>Methods in Enzymology</u> , 107:377-388, (Wold <i>et al.</i> ed. 1984)	
	C4	Bird <i>et al.</i> "Single-Chain Antigen-Binding Proteins." <i>Science</i> 242:423-426(1988)	
	C5	Chang <i>et al.</i> "Pitfalls in the Use of Commercial Nonionic Detergents for the Solubilization of Integral Membrane Proteins: Sulfhydryl Oxidizing Contaminants and Their Elimination." <i>Analytical Biochem.</i> 104:112-117(1980)	
	C6	Cruikshank <i>et al.</i> "A Lipidated Anti-Tat Antibody Enters Living Cells and Blocks HIV-1 Viral Replication." <i>J Acquir Immune Defic Syndr Hum Retrovirol.</i> 14(3):193-203 (1997)	
	C7	Davies, "Protein Damage and Degradation by Oxygen Radicals, I. General Aspects." <i>J Biol Chem.</i> 262(20):9895-9901(1987)	
Examiner Signature		Date Considered	

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				Application Number	10/618350
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Sheet	2	of	2	Attorney Docket Number	MXI-285

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	C8	Davies <i>et al.</i> "Protein Damage and Degradation by Oxygen Radicals. III. Modification of Secondary and Tertiary Structure." <i>J Biol Chem.</i> 262(20):9908-9913(1987)	
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	C11	Huston <i>et al.</i> "Protein Engineering of Antibody Binding Sites: Recovery of Specific Activity in an Anti-Digoxin Single-Chain Fv Analogue Produced in <i>Escherichia Coli.</i> " <i>Proc Natl Acad Sci USA</i> 85:5879-5883(1988)	
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	C13	Kang <i>et al.</i> "Fragmentation of Human Cu,Zn-Superoxide Dismutase by Peroxidative Reaction." <i>Mol Cells.</i> 7(4):553-558(1997)	
	C14	Kocha <i>et al.</i> "Hydrogen Peroxide-Mediated Degradation of Protein: Different Oxidation Modes of Copper- and Iron-Dependent Hydroxyl Radicals on the Degradation of Albumin." <i>Biochim Biophys Acta.</i> 1337:319-326(1997)	
	C15	Packer <i>et al.</i> (editors) "Oxygen Radicals in Biological Systems Part B: Oxygen Radicals and Antioxidants." in <i>Methods in Enzymology</i> , 186:14, 16, 41-42(1990)	
	C16	Reiter, "Cytoprotective Properties of Melatonin: Presumed Association with Oxidative Damage and Aging." <i>Nutrition.</i> 14(9):691-696(1998)	
	C17	Reubsaet <i>et al.</i> "Analytical Techniques Used to Study the Degradation of Proteins and Peptides: Chemical Instability." <i>J Pharm Biomed Anal.</i> 17:955-978(1998)	
	C18	Volkin <i>et al.</i> "Degradative Covalent Reactions Important to Protein Stability." <i>Mol Biotechnol.</i> 8:105-122(1997)	
	C19	Ward <i>et al.</i> "Binding Activities of a Repertoire of Single Immunoglobulin Variable Domains Secreted from <i>Escherichia Coli.</i> " <i>Nature.</i> 341:544-546(1989)	
	C20	Whitaker <i>et al.</i> "Proteins in Alkaline Solution." In <i>Chemical Deterioration of Protein J. ACS Symp Ser.</i> 123:147-149(1980)	
Examiner Signature		Date Considered	

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